

MEDICAL DEVICE PREEMPTION: A REASONABLE AVENUE OF TORT REFORM?

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INTRODUCTION

In recent years, tort reform has been a topic of debate between lawyers, politicians, and scholars. In the most recent Presidential campaign, George W. Bush focused on tort reform as one issue that our nation should address.¹ Proponents of tort reform focus on rising medical costs and exorbitant insurance premiums doctors must pay to argue for reform through avenues such as placing a cap on tort damages.² Much of the mainstream tort reform debate centers around malpractice claims against doctors; however, often left out of the discussion is devising measures to protect medical device and drug manufacturers from liability. One means of protection for these manufacturers is the affirmative defense of preemption.³ Congress

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¹ Dan Zegart, *Tort Reform Advocates Play Fast and Loose With the Facts*, MONTANA LAWYER, February 2005, at 30.

² See e.g. Geoff Boehm, *Debunking Medical Malpractice Myths: Unraveling The False Premises Behind "Tort Reform,"* 5 YALE J. HEALTH POL'Y L. & ETHICS 357 (2005) (Arguing against placing caps on victim's damages award and instead focus on regulating the insurance industry).

³ See DAVID G. OWEN, PRODUCTS LIABILITY LAW § 14.4 (2005) ("When enacting product safety legislation, Congress normally vests regulatory authority over the matter in a federal administrative agency, often specifying, in a preemption clause, that state law may not interfere with safety standards or "requirements" in the statute itself or, more typically, as promulgated by the federal agency").

has drafted preemption provisions into many of its regulatory schemes, which serve to limit common law tort claims and effectuate tort reform “through the back door.”⁴

Within the realm of medical devices, the Supreme Court has refused to allow the preemption defense for devices receiving certification under the 510(k) process.⁵ While a vast majority of Class III medical devices are marketed using the 510(k) process, the Court has yet to speak on the issue of preemption with regard to medical devices approved under the pre-market approval process (“PMA”). When and if the Court hears the issue, it should agree with 7th Circuit analysis, and hold that completing the PMA process shields medical device manufacturers from common law tort liability through the affirmative defense of preemption. Doing so will provide a reasonable avenue of tort reform, while also balancing the competing concerns of developing innovative medical devices with protecting the public from injuries resulting from medical devices.

Part I of this article will provide a historical background to the issue of preemption in medical device cases. Preemption arguments have been reborn following the Supreme Court’s decision in *Cipollone v. Liggett Group, Inc.*⁶ Part II will review the case of *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 484-85 (7th Cir. 2005) and its predecessor, *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997). These cases firmly established the rule that common law tort claims against PMA devices are preempted. Part III will discuss the broad procedural and policy implications of the 7th Circuit’s rationale. By balancing competing policy interests, the 7th Circuit has adopted the proper rule. Part IV will analyze the arguments against the

⁴ See e.g. 7 U.S.C. § 136v(b) (2006) (Preemption provision of the Federal Insecticide, Fungicide and Rodenticide Act); 49 U.S.C. § 30103(b)(1) (2006) (Preemption provision of the National Traffic and Motor Vehicle Safety Act); 21 U.S.C. 360(k) (2006) (Preemption provision of the Medical Device Amendments to the Food Drug and Cosmetic Act); 49 U.S.C. § 4306 (2006) (Preemption provision of the Federal Boat Safety Act); 15 U.S.C. § 2075(a) (2006) (Preemption provision of the Consumer Product Safety Act).

⁵ *Medtronic v. Lohr*, 518 U.S. 470 (1996).

⁶ 505 U.S. 504 (1992).

7th Circuit's reasoning, and discuss specific problems with various courts' analysis. Part V will analyze whether the Supreme Court is likely to adopt the 7th Circuit's reasoning, especially in light of the changes to the Court since its last relevant decision in 1996. The addition of Chief Justice John Roberts and Justice Samuel Alito, will have an impact on the future of preemption analysis within the medical device contest. Examining their histories with medical device preemption may shed some light on how they will decide the issue.

I. BACKGROUND

“No issue in modern products liability law is more important, or more inscrutable, than the doctrine of federal preemption.”⁷ Until the Supreme Court's 1992 decision in *Cipollone v. Liggett Group, Inc.*, offering the affirmative defense of express federal preemption was not, in most cases, a successful venture.⁸ Since *Cipollone*, express federal preemption has been a hotly contested issue in cases involving the regulation of pesticides and insecticides, motor vehicles, air bags, recreational boats, consumer products, workplace products, drugs, and, as discussed below, medical devices.⁹

A. *History of the Medical Device Amendments*

⁷ Owen, *supra* note 3 at 895.

⁸ *Id.* at 901.

⁹ Owen, *supra* note 3 (citing numerous cases involving preemption within these contexts); *See e.g.* Williams v. Dow Chemical Co., 255 F. Supp. 2d 219 (S.D.N.Y. 2003) (preemption analysis of federal regulation of pesticides and insecticides); Freightliner Corp. v. Myrick, 514 U.S. 280 (1995) (preemption analysis of federal regulation of motor vehicles); Geier v. American Honda Motor Co., 529 U.S. 861 (2000) (preemption analysis of federal regulation of air bags); Sprietsma v. Mercury Marine, 537 U.S. 51 (2002) (preemption analysis of federal regulation of recreational boats); Cortez v. MTD Prod., Inc., 927 F. Supp. 386 (N.D. Cal. 1996) (preemption analysis of federal regulation of consumer products); Pedraza v. Shell Oil Co., 942 F.2d 48 (1st Cir. 1991) (preemption analysis of federal regulation of workplace products); Bell v. Lollar, 791 N.E.2d 849 (Ind. Ct. App. 2003) (preemption analysis of federal regulation of drugs); Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) (preemption analysis of federal regulation of medical devices).

In 1976, Congress enacted the Medical Device Amendments (“MDA”) to the Food Drug and Cosmetic Act (“FDCA”), in which the Food and Drug Administration (“FDA”) was appointed to regulate the safety and effectiveness of medical devices.¹⁰ Some medical devices, originally touted as safe and effective, were posing severe health risks to consumers, including death.¹¹ Responding to its grant of authority and the growing concern for consumer safety, the FDA created three different categories of medical devices, organized according to their potential safety risks. Class I devices, such as tongue depressors, receive a minimal level of regulation because they pose minimal risk to the public.¹² Class II devices, such as tampons or hearing aids, are subjected to “special controls” because of the potentially more harmful results of their use.¹³ Class III devices, such as pacemakers or artificial hearts, are regulated subject to the most exacting controls, because these devices pose a “potential unreasonable risk of illness or injury.”¹⁴ To market a Class III device, a manufacturer must present enough evidence to instill in the FDA a “reasonable assurance” that the device is safe and effective for consumers.¹⁵

The FDA requires all Class III medical devices to receive “pre-market approval.”¹⁶ To obtain approval under the PMA process, a manufacturer must submit many documents to the FDA: “a bibliography of all reports concerning the device’s safety and effectiveness, an outline of the device’s components and properties, a

¹⁰ See 21 U.S.C. § 360 (2006).

¹¹ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996) (examining various hearings before Congress in 1973, during which Congress examined devices such as the Dalkon Shield, a intrauterine contraceptive device, that was declared to be safe and effective, but led to a high percentage of inadvertent pregnancies, serious infections and even death. Other devices Congress examined that potentially posed safety concerns included catheters, artificial heart valves, defibrillators and pacemakers).

¹² Owen, *supra* note 3 at 910.

¹³ *Id.*

¹⁴ 21 U.S.C. § 360c(1)(C) (2006).

¹⁵ 21 U.S.C. § 360e(d)(2) (2006).

¹⁶ 21 U.S.C. § 360e (2006).

description of the manufacturing process, safety data, samples of the device, copies of all proposed labeling,” along with any other FDA required material.¹⁷ Once this information is received, the FDA then spends an average of 1,200 hours reviewing the device, requesting further testing and information, and imposing other conditions that must be met before the device reaches the market.¹⁸ Often, the FDA will require changes be made to the device or its warnings before it can receive full approval. For example, in *Brooks v. Howmedica, Inc.*, the Eighth Circuit examined the regulations and requirements placed on Simplex bone cement during the approval process.¹⁹ The court noted that the FDA had required specific warning language both during and after the approval process.²⁰ When the FDA does not alter a PMA application, it has determined that the manufacturer-drafted warnings, labeling, design, etc. are sufficient and in need of no revision.

While the PMA process is generally required before Class III devices can be placed in the market, the rule has two significant exceptions. “These exceptions have developed a propensity for

¹⁷ *Martin v. Teletronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095 (6th Cir. 1997); *See also* 21 C.F.R. § 814.20 (2006).

¹⁸ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-79 (1996).

¹⁹ 273 F.3d 785 (8th Cir. 2001).

²⁰ *Id.*; *See also* *Horn v. Thoratec Corp.*, 376 F.3d 1363 (3d Cir. 2004) (examining the PMA process for the HeartMate ventricular assist device. From 1975-1985 the manufacturer conducted studies on live animals and human cadavers. In 1985, the HeartMate was granted an investigational device exemption from the FDA to begin clinical trials. For seven years clinical trials were conducted at hospitals. During this period the manufacturer submitted extensive information to the FDA, and the FDA responded with numerous inquiries into the safety and effectiveness of the device. The FDA, after review, also approved design changes that were made to prevent leaks from the HeartMate’s screw ring. In 1992, the manufacturer submitted its PMA application to the FDA. For two years, the manufacturer submitted a substantial amount of amendments to the device and responded to numerous FDA questions. In 1994, after extensive review, the HeartMate received final approval under the PMA process, in the form specified in the final application).

swallowing the rule.”²¹ First, devices on the market prior to May 28, 1976 are grandfathered in from this requirement, until the FDA completes the PMA process for such devices.²² Second, manufacturers may be able to enter a limited form of review called “premarket notification.”²³ This type of FDA review, also known as “the § 510(k) process,” is available to manufacturers when their device is “substantially equivalent” to other devices on the market prior to the MDA in 1976.²⁴ On average, the FDA spends only twenty hours of review to determine whether a device may be initially marketed under the § 510(k) process.²⁵

When Congress enacted the MDA, it included an express preemption provision, as it does with many other regulatory statutes.²⁶ Because of the different avenues of review a device can take before entering the market, courts have struggled with when to apply the preemption provision. The language of the preemption provision states the following:

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

²¹ *Mitchell v. Collagen Corp.*, 126 F.3d 902, 905 (7th Cir. 1997); *See also Horn*, 376 F.3d at 1367 (noting that in 2003, only 54 of 9,872 medical device applications to the FDA were requesting PMA review. In 2002 only 49 of 10,323 medical device applications requested PMA review).

²² *Mitchell*, 126 F.3d at 905.

²³ *Lohr*, 518 U.S. at 478.

²⁴ *Id.*

²⁵ *Id.*

²⁶ *See* statutes cited *supra* note 4.

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.²⁷

Thus, should a state seek to impose a “requirement” on a device that differs from a requirement already placed on the device during the device review process, such a requirement would be preempted. This provision has required courts to struggle with two major questions: 1) what constitutes a state requirement, and 2) what, if any, federal requirements exist during device review?

B. Scope of Preemption – Medtronic v. Lohr

The Supreme Court first analyzed the scope of the MDA preemption provision in *Medtronic, Inc. v. Lohr*.²⁸ Lora Lohr depended on a pacemaker to properly regulate her heart.²⁹ In 1987, she had a Medtronic pacemaker implanted to serve this function.³⁰ However, the pacemaker failed in 1990, requiring immediate surgery.³¹ Lohr’s physician stated that the type of lead in the pacemaker was the likely cause of failure.³² Medtronic had received clearance from the FDA under the 510(k) process to market the device.³³ Lohr and her husband brought a common law tort claim against Medtronic alleging negligence and strict liability.³⁴ A divided court held that the 510(k) process of device review did not create any federal requirements on the pacemaker and thus Lohr’s common-law

²⁷ 21 U.S.C. § 360(k) (2006).

²⁸ 518 U.S. 470.

²⁹ *Id.* at 480.

³⁰ *Id.*

³¹ *Id.* at 481.

³² *Id.*

³³ *Id.* at 480.

³⁴ *Id.* at 481.

tort claims could not be preempted.³⁵ Accordingly, preemption arguments under 510(k) review have ended. Nevertheless, the Court has yet to answer the question of preemption under the more rigorous PMA avenue of device review. The three opinions in *Lohr* help shed some light on arguments made for both sides.

1. Justice Stevens' Opinion

Justice Stevens, joined by Justices Kennedy, Souter and Ginsburg, wrote for a majority of the Court in parts I, II, III, V, and VII of his opinion.³⁶ At the outset, Justice Stevens examined the differences between the 510(k) process exemption and the PMA process. “The 510(k) process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the 510(k) review is completed in an average of 20 hours.”³⁷ Discussing the various causes of action, a unanimous Court held that the defective design claims were not preempted because the 510(k) process was only focused on equivalence. In fact, Medtronic only had to comply with “general standards—the lowest level of protection [to manufacturers]—applicable to *all* medical devices.”³⁸ The Court found that the 510(k) process thus could not constitute a federal requirement “specific to a device.”³⁹

Later, the Court stated that even if 510(k) did impose requirements, and state common law claims could be considered requirements, the claims that Medtronic violated specific FDA regulations could be maintained.⁴⁰ For example, the Court held that the manufacturing and labeling claims were not preempted, because

³⁵ *Id.* at 492-503.

³⁶ Justice Breyer concurred with the opinion except for parts IV or VI.

³⁷ *Lohr*, 518 U.S. at 478-479 (referring to the PMA process and “rigorous” and noting that “in 1990, 80% of the Class III devices were being introduced through the 510(k) process and without PMA review”).

³⁸ *Id.* at 493-94.

³⁹ *Id.*

⁴⁰ *Id.* at 495.

the FDA-maintained device regulations—both in the manufacturing and labeling areas—were requirements of general applicability and could not be said to be specific to the device in question.⁴¹

Writing for a plurality of the Court in Parts IV and VI of his opinion, Justice Stevens disagreed with Medtronic’s argument that Congress intended to preclude all common law causes of actions:

If Congress intended to preclude all common-law causes of action, it chose a singularly odd word with which to do it. The statute would have achieved an identical result, for instance, if it had precluded any “remedy” under state law relating to medical devices. ‘Requirement’ appears to presume that the State is imposing a specific duty on the manufacturer.⁴²

The plurality argued that the MDA would rarely preempt common law causes of action, because the word requirement “is linked with language suggesting that its focus is device-specific enactments of *positive law by legislative or administrative bodies*, not the application of general rules of common law by judges and juries.”⁴³

2. Justice O’Connor’s Dissenting Opinion

Justice O’Connor, joined by Chief Justice Rehnquist and Justices Scalia and Thomas, argued that a common law duty was a requirement because a common law action “operate[s] to require manufacturers to

⁴¹ *Id.* at 497-98 (examining general labeling regulations found in 21 CFR §§ 801.109 (b) and (c). Furthermore, the Court noted that “manufacturers are required to comply with ‘Good Manufacturing Practices,’ ...which are set fort in 32 sections...in the Code of Federal Regulations”).

⁴² *Lohr*, 518 U.S. at 487 (plurality) (Stevens, J.).

⁴³ *Id.* at 489 (emphasis added).

comply with common law duties.”⁴⁴ Thus, claims will be preempted “where such requirements [imposed by common law actions] would differ from those imposed by the FDCA.”⁴⁵ Justice O’Connor agreed with the Court with regards to the Lohr’s defective design claims and stated that the claim “[I]s not preempted by the [] 510(k) ‘substantial equivalency’ process,” because this process only focuses on whether devices are equivalent.⁴⁶

Justice O’Connor wrote separately from the majority with regards to the manufacturing and labeling claims.⁴⁷ She argued that the FDA’s Good Manufacturing Process (GMP) regulations,⁴⁸ and extensive labeling regulations,⁴⁹ impose federal requirements on medical devices. Because Lohr was arguing that different or additional manufacturing and labeling requirements were needed, her claims were preempted.⁵⁰ Thus, O’Connor and the other dissenting Justices took a broader view of the role of preemption in MDA cases.

3. Justice Breyer’s Opinion

Justice Breyer wrote a separate opinion concurring in part and concurring in the judgment.⁵¹ He formed a majority of the Court when opining that State common law tort actions would impose requirements specific to medical devices.⁵² To determine whether the 510(k) process imposed specific federal requirements, Breyer first

⁴⁴ *Lohr*, 518 U.S. at 510 (O’Connor, J., concurring in part and dissenting in part).

⁴⁵ *Id.* at 509.

⁴⁶ *Id.*

⁴⁷ *Id.* at 513-514.

⁴⁸ *See e.g.* 21 C.F.R. § 820.20 (2006).

⁴⁹ *See e.g.* 21 C.F.R. § 801.109 (2006).

⁵⁰ *Lohr*, 518 U.S. at 514. (O’Connor, J., concurring in part and dissenting in part).

⁵¹ *Lohr*, 518 U.S. at 503-08 (Breyer, J., concurring in part and concurring in the judgment).

⁵² *Id.* at 504-05 (agreeing with the opinion written by Justice O’Connor).

looked to the language of the preemption provision.⁵³ Finding that the wording was highly ambiguous, Justice Breyer looked elsewhere to determine which federal requirements preempted state requirements. Noting that the FDA has a special understanding of “whether state requirements may interfere with federal objectives,” Breyer argued that the FDA’s interpretation should be given some level of respect.⁵⁴ Breyer noted that the FDA could communicate its intentions through “statements in ‘regulations, preambles, interpretive statements, and responses to comments.’”⁵⁵ With respect to the FDA’s own current regulation regarding preemption, there must be a “specific [federal] requirement applicable to a particular device.”⁵⁶ Because the FDA did not impose any requirements specific to the pacemaker—that is, only general requirements—preemption did not apply.⁵⁷

C. *Post Medtronic v. Lohr* Litigation

While the Court’s judgment in *Medtronic, Inc. v. Lohr* cut-off preemption arguments in 510(k) approved devices, a whole realm of litigation regarding medical devices receiving approval under the PMA process developed. A majority of U.S. Circuit Court’s have concluded that the PMA process does impose specific federal requirements on medical devices and therefore warrants preemption of common law claims.⁵⁸ Other Circuit’s, and various other courts, argue that either the PMA process does not rise to the level of a device-specific requirement, or state common law tort actions are not within the purview of the MDA preemption provision.⁵⁹

⁵³ *Id.*

⁵⁴ *Id.* at 506.

⁵⁵ *Id.*; *See also supra* note 146.

⁵⁶ *Lohr*, 518 U.S. at 506 (Breyer, J., concurring in part and concurring in the judgment); *See* CFR § 808.1(d) (2006).

⁵⁷ *Lohr*, 518 U.S. at 507 (Breyer, J., concurring in part and concurring in the judgment).

⁵⁸ *See* cases cited *infra* note 106.

⁵⁹ *See* cases cited *infra* note 107.

II. THE SEVENTH CIRCUIT APPROACH TO PREEMPTION AND PMA

Following *Medtronic, Inc. v. Lohr*, the 7th Circuit held that specific requirements are placed on medical devices during the PMA process.⁶⁰ Furthermore, common law tort claims, which would impose requirements different from or in addition to those already imposed during the PMA process, would be preempted.⁶¹ Recently, the 7th Circuit re-affirmed this precedent in *McMullen v. Medtronic, Inc.*, and analyzed whether two FDA regulations preempted common law tort claims.⁶²

A. *Mitchell v. Collagen* – PMA Preempts Most Common Law Claims.

In 1988, Barbara Mitchell received several injections of Zyderm, a collagen-based product used to fill in tissue under the skin when the tissue is lost due to injury, age, infection or other diseases.⁶³ Zyderm had received original PMA approval in 1981 and additional PMA approval when the FDA conducted a re-review from 1991-1992. Sometime after the injections, Mitchell developed serious medical complications.⁶⁴ She brought a complaint against Collagen, alleging that Collagen was liable for her complications under theories of strict liability, negligence, fraud, mislabeling, misbranding, adulteration and breach of warranty.⁶⁵ During the 7th Circuit's first review of the case in 1995, it held that the MDA allowed for at least some state common law tort claims to be preempted.⁶⁶ Furthermore, because specific requirements were placed on medical devices during the PMA process,

⁶⁰ *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997).

⁶¹ *Id.*

⁶² 421 F.3d 482 (7th Cir. 2005).

⁶³ *Mitchell*, 126 F.3d at 905.

⁶⁴ *Mitchell v. Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995).

⁶⁵ *Mitchell*, 126 F.3d at 906.

⁶⁶ *Mitchell*, 67 F.3d 1268.

the Court held that most of Mitchell's claims would be preempted.⁶⁷ The Mitchell's appealed to the Supreme Court, which granted certiorari and then remanded the case to the Seventh Circuit to reconsider the Mitchell's claims in light of the intervening *Medtronic v. Lohr* decision.

Upon re-review, the 7th Circuit stood by its initial decision. After analyzing the various opinions in *Lohr*, the court noted that the Supreme Court's decision was not without its own ambiguities.⁶⁸ The court began sifting through these ambiguities to reach its ultimate decision. First, the court noted that a majority of the Supreme Court—Justice O'Connor and those joining her opinion, as well as Justice Breyer in his concurring opinion—held that the MDA preempted at least some state common law claims.⁶⁹

Second, the court noted that the PMA process is substantially different than the 510(k) process involved in *Medtronic, Inc. v. Lohr*.⁷⁰ Because of the rigors of the PMA process, the court held that the process imposes specific federal regulation or requirements on the medical devices.⁷¹ The court found that with respect to the PMA process “the federal government...has ‘weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.’”⁷²

⁶⁷ *Id.* (holding that one fraud claim and a breach of express warranty claim would not be preempted, since they did not add any requirement different from or in addition to requirements already imposed by the FDA).

⁶⁸ *Mitchell*, 126 F.3d at 910 (“[T]he holding in *Medtronic* contains several ambiguities that impair our ability to perceive with absolute clarity the path that the Court has chosen for us to follow.”).

⁶⁹ *Id.*

⁷⁰ *Id.* at 911.

⁷¹ *Id.* (discussing *Fry v. Allergan Medical Optics* 695 A.2d 511 (R.I. 1997)).

⁷² *Mitchell*, 126 F.3d at 910 (quoting from *Medtronic v. Lohr*, 518 U.S. 470, 501 (1996)).

Third, the court discussed which types of common law claims would be preempted by the PMA process. The court stated that “[I]t is necessary to examine the state law cause of action at a sufficiently precise level of generality to determine whether the final judgment of the state court would impose on the manufacturer a burden incompatible with the requirements imposed by the FDA.”⁷³ In other words, so long as the plaintiff’s claim alleged a departure from FDA-imposed standards, the claim would not be preempted; however, if the claim alleged that the manufacturer failed to make adjustments or corrections to the device not required by the FDA, the claim would be preempted insofar as it would impose a requirement different from or in addition to those already required by the FDA.⁷⁴

When the court examined the Mitchell’s claims, it determined that the strict liability, negligence, mislabeling, misbranding, adulteration, fraud and implied warranty claims were all preempted. Each of these claims, if successful, would impose requirements on Zyderm that were different from or in addition to those already placed on Zyderm during the PMA process.⁷⁵ While most avenues of recovery were closed by preemption, the court did state that had there been an express warranty, Mitchell could recover against Collagen for breach of any express warranty.⁷⁶

B. McMullen v. Medtronic – Reaffirming Mitchell’s Reasoning.

Recently, the 7th Circuit had the opportunity to revisit its decision from *Mitchell v. Collagen Corp.*⁷⁷ In *McMullen v. Medtronic, Inc.* the

⁷³ *Mitchell*, 126 F.3d at 912 (relying on the reasoning of Judge Rovner from *Chambers v. Osteonics Corp.* 109 F.3d 1243 (7th Cir. 1997), a case dealing with the preemptive effect of the MDA under the investigational device exemption (IDE) for Class III medical devices).

⁷⁴ *Mitchell*, 126 F.3d at 912-915.

⁷⁵ *Id.*

⁷⁶ *Id.* (noting that the Mitchell’s had failed to specify they were relying on such a claim, and that the Mitchell’s had never stated that Collagen had given them an express warranty of the product.)

⁷⁷ 126 F.3d 902.

court examined the case of Jack and Barbara McMullen, who had brought suit against Medtronic claiming that Medtronic had breached its post sale duty to warn.⁷⁸ In May 2000, Jack McMullen opted to have two of Medtronic's Activas implanted into his brain.⁷⁹ He had been suffering from Parkinson's Disease since 1985, and the Medtronic Activa was being successfully used in the suppression of tremors for those diagnosed with Parkinson's Disease. The Activa is a class III medical device that received full PMA approval in 1997.⁸⁰

During the PMA process, the FDA issued at least two requirements on the Activa. First, Medtronic was required to track the name and contact information of patients implanted with Activa.⁸¹ Second, the FDA required Medtronic to issue specific warnings regarding the terms "electrocautery" and "diathermy" in its manuals.⁸² The warnings the FDA required were as follows:

Tell your dentist where your IPG is implanted, so he or she can take precautions with dental drills and ultrasonic probes used to clean your teeth. These devices should not be used directly over the implant site. Therapeutic ultrasound, electrolysis, radiation therapy, and electrocautery also should not be used directly over the implant site...Diathermy treatments that are sometimes used for muscle relaxation may affect the

⁷⁸ 421 F.3d 482, 484-85 (7th Cir. 2005).

⁷⁹ *Id.* at 485.

⁸⁰ *Id.* at 484-85.

⁸¹ *Id.*

⁸² *Id.* (defining "electrocautery" as the burning or searing of tissue by means of an electrically heated instrument, and defining "diathermy" as therapeutic local heating by means of passing electric currents through tissue).

neurostimulator output and/or damage its electronics.⁸³

Following implantation, Jack Mullen “experienced an excellent remediation of his Parkinson’s symptoms.”⁸⁴ However, in March of 2001, McMullen visited his dentist and underwent a procedure that may have involved diathermy or electrocautery.⁸⁵ Following the procedure, he experienced a reduction in the ability of the Activa to sufficiently control his tremors.⁸⁶ After undergoing more surgeries to replace various components of the Activas, McMullen still did not receive the same beneficial effects he had before the dentist visit.⁸⁷ McMullen argued that the procedure at the dentist office led to damaged brain tissue surrounding the devices.⁸⁸

The basis for McMullen’s argument stemmed from a report Medtronic learned of in January of 2001. The report detailed a 70 year old individual with Parkinson’s Disease that had been implanted with one of Medtronic’s Activa devices. The individual received diathermy treatment from his dentist following oral surgery, and subsequently went into a coma during the treatment. Furthermore, the report listed the possible cause of the coma as damaged brain tissue around the wires to the device.⁸⁹ In May 2001, following further investigation of the report, Medtronic sent letters to both physicians and patients warning them that individuals implanted with an Activa “cannot” have any diathermy performed anywhere on their body, because the “energy from diathermy [could] be transferred through [their] system, [could] cause tissue damage and [could] result in severe injury or death.”⁹⁰

⁸³ *Id.* at 485.

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.* at 485-86.

⁹⁰ *Id.*

McMullen argued that Medtronic breached its post sale duty to warn, namely because the warning sent out by Medtronic was not received before he had gone to the dentist in March of 2001.⁹¹ Using two FDA regulations—21 C.F.R §§ 821.1 and 814.39—McMullen argued that his claim could not be preempted because it would not impose requirements on Medtronic that were different or additional to those regulations it was already obligated to follow.⁹²

Turning to the language of the regulations, the court found that McMullen’s claims would still be preempted. First, the court noted that 21 C.F.R. § 821.1 did not impose a requirement on the manufacturer “to make warning or recall decisions unilaterally, nor does it authorize the manufacturer to do so.”⁹³ Second, the court noted that 21 C.F.R. § 814.39 “permits a manufacturer to temporarily amend a warning pending FDA approval of the proposed changes.”⁹⁴ Thus, it does not *require* a manufacturer to temporarily amend its warning. Therefore, Medtronic did not depart from FDA guidelines.

The court reaffirmed its decision from *Mitchell v. Collagen* and held: 1) the PMA device approval process imposes specific federal requirements on manufacturers; 2) McMullen’s state law tort claim, if successful, would have imposed on Medtronic a duty to provide an additional warning between January 2001 and March 2001; and 3) because the regulations submitted by McMullen do not require a manufacturer to issue a temporary warning, McMullen’s claim would be imposing an additional requirement on Medtronic that was not found in the FDA regulation. Thus, the court held the claim was preempted.⁹⁵

⁹¹ *Id.* at 486.

⁹² *Id.* at 489.

⁹³ *Id.* (finding that pursuant to 21 U.S.C. §§ 360h(a) and (e) the Secretary of Health and Human Services has the discretion to issue or withhold warnings concerning medical devices based on the Secretary’s assessment of the risks); 21 C.F.R. § 821.1 (2006).

⁹⁴ *McMullen*, 421 F.3d at 489; 21 C.F.R. § 814.39 (2006).

⁹⁵ *McMullen*, 421F.3d at 490.

III. WHY THE SEVENTH CIRCUIT IS CORRECT

A common sense approach to what occurs during the PMA process should lead one to conclude that the FDA imposes *requirements* on a device during PMA.⁹⁶ Furthermore, since specific requirements already exist for PMA medical devices, allowing state tort claims against the manufacturers of these devices will circumvent congressional intent.⁹⁷ Manufacturers would have to spend exorbitant amounts of money in litigation and in trying to comply with each state's own interpretation of what is or is not necessary for the device.

Looking beyond mere common sense analysis of the general two-part test for preemption, there are several broader policy and procedural concerns that favor adopting the 7th Circuit's rationale. One procedural benefit the 7th Circuit's rationale provides is a bright line rule, which are favored by courts for judicial efficiency. A rule requiring case by case determinations would clog judicial dockets with costly litigation, not only for the parties involved, but for society at large. The push for bright line rules can be seen in the Supreme Court's *Medtronic v. Lohr* decision--any manufacturer that markets its device through the 510(k) process will not be afforded the protections of a preemption defense.⁹⁸ Nevertheless, because each Justice in *Medtronic* felt that "Congress intended the MDA to pre-empt at least some state law," one can speculate that the Court may have been implicitly talking about the PMA process.⁹⁹

⁹⁶ See e.g. *Brooks v. Howmedica, Inc.* 273 F.3d 785 (8th Cir. 2001) (examining how the FDA required specific warning language to be added to the product); *McMullen*, 421 F.3d at 484-85 (examining at least two requirements the FDA required the device to follow before allowing it to be marketed).

⁹⁷ See H.R. REP. NO. 94-853, at 45-46 (1976) ("[I]f a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened").

⁹⁸ *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

⁹⁹ *Id.* at 484 (Stevens, J.); *Id.* at 503 (Breyer, J., concurring in part and concurring in the judgment) ("[T]he MDA will sometimes pre-empt a state law tort suit. I basically agree with Justice O'Connor's discussion of this point."); *Id.* at 509 (O'Connor, J., concurring in part and dissenting in part) ("I conclude that state

While many bright line rules sweep too broadly, the 7th Circuit's PMA preemption rule actually balances the competing policy goals of the MDA: 1) guaranteeing medical device innovation in the future through uniform device regulation, and 2) protecting the public by not allowing medical devices to be marketed until they are safe and effective.¹⁰⁰ As discussed, the Supreme Court has already forbid preemption analysis when devices are marketed using the 510(k) process.¹⁰¹ Furthermore, a vast majority of all Class III medical devices currently on the market receive approval through this process.¹⁰² Thus, only in an extremely small percentage of cases would a consumer's claim against a medical device manufacturer be foreclosed through preemption. Since most PMA medical devices are truly innovative, that is not substantial equivalents, their device manufacturers should be afforded a significant level of protection to ensure future innovative growth.

Assuming that the Supreme Court agreed with the 7th Circuit bright line rule, medical device manufacturers would be given an incentive to complete the PMA process—the defense of preemption should their device become subject to litigation. Such an incentive would not only benefit the manufacturers of the device, but it would

common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA").

¹⁰⁰ See generally Brief for The Center for Patient Advocacy and the California Health Care Institute as Amici Curiae Supporting Petitioner/Cross-Respondent, *Medtronic v. Lohr*, 518 U.S. 470 (1996) (Nos. 95-754, 95-886) (examining the Senate and House of Representatives Reports to show Congress' intent to adequately balance these goals. Also mentioning numerous statements made during Congressional debates and hearings on the MDA in 1990).

¹⁰¹ *Lohr*, 518 U.S. 470.

¹⁰² *Id.* at 479 ("In 1983, for instance, a House Report concluded that nearly 1,000 of approximately 1,100 Class III devices that had been introduced to the market since 1976 were admitted without any PMA review . . . [T]he House reported in 1990 that 80% of new Class III devices were being introduced . . . without PMA review"); *Horn v. Thoratec Corp.*, 376 F.3d 1363 (3d Cir. 2004) (noting that in 2003, only 54 of 9,872 medical device applications to the FDA were requesting PMA review. In 2002 only 49 of 10,323 medical device applications requested PMA review).

also benefit the public. To illustrate, because more manufacturers may opt to complete the more rigorous PMA process, more devices would then receive heightened review from the FDA before entering the market. The logical end would be that instead of having to litigate for injuries sustained using 510(k) devices, consumers may not become injured in the first place due to the extensive PMA review.

Insulating this small percentage of medical device manufacturers from tort liability provides a reasonable measure of tort reform in our litigious society. Without the protection of a preemption defense, manufacturers of PMA devices will have to make tough decisions regarding the future of their respective companies. For instance, some medical device manufacturers may be forced to declare bankruptcy.¹⁰³ Others will be forced to pull their devices from the market without authoritative proof that the device is harmful.¹⁰⁴ Liability concerns may cause some companies to forego research or marketing of potential breakthroughs in medical technology.¹⁰⁵ Each of these

¹⁰³ Brief Supporting Petitioner/Cross Respondent, *supra* note 100, at 15-16 (noting that breast implant litigation forced Dow Corning into Chapter 11 bankruptcy even though the company made less than one percent of its revenue from breast implant sales, and numerous studies had shown that the silicone breast implants were not the cause of plaintiffs' afflictions (citing, *e.g.* Charles H. Hennekens et al., *Self-Reported Breast Implants and Connective-Tissue Diseases in Female Health Professionals: A Retrospective Cohort Study*, 275 J. AM. MED. ASS'N 616, 621 (1996))).

¹⁰⁴ Brief Supporting Petitioner/Cross Respondent, *supra* note 100, at 20-21 (noting that Merrell Dow was forced to take its popular drug Bendectin off the market because of liability concerns, even though there was no proof that Bendectin was harmful to patients (citing, *e.g.* *Daubert v. Merrell Dow Pharm.*, 43 F.3d 1311, 1314 (9th Cir. 1995))); *See also* Joan E. Shreffler, Comment, *Bad Medicine: Good-Faith FDA Approval as a Recommended Bar to Punitive Damages in Pharmaceutical Products Liability Cases*, 84 N.C. L. REV. 737 (2006) (examining the current litigation against pharmaceutical giant Merck and its impact upon punitive damage awards).

¹⁰⁵ Brief Supporting Petitioner/Cross Respondent, *supra* note 100, at 18-19 (noting that liability concerns may cause some manufacturers to cease developing important medical advancements (citing, *e.g.* Peter W. Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 286-88 & n.49 (1985))).

scenarios stifles medical device or drug innovation. While there will undoubtedly be costs associated with allowing preemption of PMA devices, whether physical, economical, social or emotional, the end benefits to society – creating a better healthcare system and saving more lives – outweigh these concerns.

IV. ARGUMENTS AGAINST THE COURT’S REASONING

The 7th Circuit’s decision in *Mitchell v. Collagen, Corp.* and *McMullen v. Medtronic, Inc.* constitute the “majority rule” amongst U.S. Circuit courts that have decided this issue.¹⁰⁶ However, there are many courts that have held that the PMA process does not preempt state common law tort claims.¹⁰⁷ Throughout these decisions there are several recurring arguments. Upon review, each of these arguments are faulty and are easily countered.

Currently, the Eleventh Circuit United States Court of Appeals is the highest court that disagrees with 7th Circuit PMA analysis.¹⁰⁸ In *Goodlin v. Medtronic, Inc.*, the 11th Circuit held that the PMA process does not preempt common law tort claims.¹⁰⁹ Much like the *Medtronic, Inc. v. Lohr* case, Lisa Goodlin brought a claim against Medtronic alleging that a pacemaker she had used was negligently

¹⁰⁶ See *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004); *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001) (en banc, 7-2 decision); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir. 1993).

¹⁰⁷ See *Goodlin v. Medtronic, Inc.* 167 F.3d 1367 (11th Cir. 1999); *Woods v. Gliatech, Inc.* 218 F. Supp. 2d 802, 808 (W.D. Va. 2002); *Fiore v. Collagen Corp.*, 930 P.2d 477, 482 (Ariz. 1996); *Lakie v. Smith-Kline Beecham* 965 F. Supp. 49, 54 (D.D.C. 1997); *Walker v. Johnson & Johnson Vision Prods.*, 552 N.W. 2d 679, 684-685 (Mich. Ct. App. 1996); *Connelly v. Iolab Corp.*, 927 S.W. 2d 848, 854 (Mo. 1996); *Green v. Dolsky*, 685 A.2d 110, 116 (Pa. 1996); *Wutzke v. Schwaegler*, 940 P.2d 1386, 1391-92 (Wash. Ct. App. 1997); *Weiland v. Teletronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999); *Haidak v. Collagen Corp.*, 67 F. Supp. 2d 21 (D. Mass. 1999).

¹⁰⁸ *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999).

¹⁰⁹ *Id.*

designed.¹¹⁰ The only difference in Goodlin’s case was that the alleged defect in the pacemaker stemmed from a type of lead wire that had been approved under PMA, rather than through the 510(k) process.¹¹¹ During the “extensive” PMA review, Medtronic conducted numerous trials of the lead wire in the pacemaker and submitted the results to the FDA.¹¹² In turn, the FDA asked for further information about the lead wire and requested further testing before issuing a final PMA.¹¹³ More than three years after submitting the lead wire to the FDA, Medtronic received final PMA.¹¹⁴

The main contention made by the *Goodlin* Court was that “[T]o prevail . . . Medtronic must identify a specific federal requirement imposed on its particular device that would preempt any conflicting or additional state requirement inherent in a jury verdict in Goodlin’s favor.”¹¹⁵ The court examined the behavior of the FDA during the PMA process, and noted that to be considered a requirement, the FDA “[M]ust [impose] some ascertainable condition.”¹¹⁶ Because the FDA only asked for information and testing to be completed, and “[I]ssue[d] no regulation, order or any other statement of its substantive benchmark,” the court argued no requirement was imposed.¹¹⁷

The 11th Circuit appears to argue then, that had the FDA required certain language be added to warnings or other labeling, or had the FDA made a design change to the pacemaker, the claim would then be preempted because a substantive requirement was issued. However,

¹¹⁰ *Id.* at 1369.

¹¹¹ *Id.* at 1368.

¹¹² *Id.* at 1369.

¹¹³ *Id.* at 1370.

¹¹⁴ *Id.*

¹¹⁵ *Id.* at 1372.

¹¹⁶ *Id.* at 1374.

¹¹⁷ *Id.* at 1375; *See also* Michael P. DiNatale, *Patients Beware: Preemption of Common Law Claims Under the Medical Device Amendments*, 39 J. MARSHALL L. REV. 75 (arguing that the 11th Circuit’s decision was correct, yet failing to examine the numerous cases where the FDA has required specific warnings, labeling or design changes to devices during the PMA process).

this line of reasoning is disingenuous for two reasons. First, the FDA does issue substantive changes to many products that undergo PMA review.¹¹⁸ Second, if the FDA is required to issue substantive requirements on a device's warnings, labeling or design to constitute a requirement, a manufacturer is given an incentive to draft poor warnings or labels, or poorly design a minor aspect of the device. In turn, the FDA will then require certain changes to substantive elements of the device's warnings, labeling or design, triggering preemption of common law tort claims.

Certainly, Congress did not intend to reward manufacturers with the affirmative defense of preemption if, for example, the manufacturer submitted poorly drafted warnings to the FDA, knowing that they would be changed. A better rationale to this 11th Circuit misstep is that the FDA's silence with regard to substantive elements of a device's warnings, labels or design, means that the FDA has found the existing substantive elements of the device to be beyond reproach. In other words, the FDA's silence alone creates requirements on a device, as the manufacturer must comply with the approved warnings, labels or design submitted to the FDA.

Other lower courts have attempted different arguments in attacking the 7th Circuit rationale. One line of argument focuses on Part IV of Justice Stevens plurality opinion in *Medtronic* for guidance, misinterpreting this portion of the opinion for the holding of the court. For example, in *Lakie v. Smith-Kline Beecham*, the District of Columbia District Court gave great weight to the plurality opinion in Part IV of *Medtronic, Inc. v. Lohr*, and held that the PMA does not preempt common law claims because the Supreme Court had "held that Congress did not intend to bar state common law causes of action for injuries resulting from defective medical devices."¹¹⁹ The court, citing Part IV of Justice Stevens opinion in *Medtronic v. Lohr*, noted that Congress was primarily concerned with preempting conflicting state statutes or regulations.¹²⁰

¹¹⁸ See e.g. cases cited *supra* note 96.

¹¹⁹ 965 F. Supp. 49, 54 (D.D.C. 1997).

¹²⁰ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 489 (1996) (plurality) (Stevens, J.).

Such an interpretation fails to consider that a majority of the Court in *Medtronic v. Lohr* held that state common law causes of action do impose requirements when the manufacturer has complied with all requirements and regulations during the PMA process and yet liability is still alleged.¹²¹ Moreover, this interpretation fails to examine the language of the FDA's own preemption provision. This provision mentions that States cannot continue with respect to "specific counterpart regulations" or "specific requirements" applicable to a device.¹²² To argue that the FDA did not intend to preempt state common law tort actions would render the phrase "specific counterpart regulations" in the preemption provision mere surplusage.

A second type of argument made by some lower courts, relying on Part V of Justice Stevens opinion, is that common law tort claims impose laws of general applicability. In other words, such laws apply to all products, not just to a specific medical device in question, and thus do not impose additional or different requirements. For example, in *Mears v. Marshall*, an Oregon Appellate Court argued that while the PMA process imposed specific federal requirements, common law causes of action only pose a general duty and would thus not constitute a specific state requirement.¹²³ The *Mears* Court looked to the language of the Court in Part V of *Medtronic*:

Similarly, the general state common-law requirements in this case were not specifically developed 'with respect to' medical devices. Accordingly, they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements . . . These general obligations are no more a threat to

¹²¹ See *supra* notes 44 & 52.

¹²² 21 C.F.R. § 808.1(d) (2006).

¹²³ *Mears v. Marshall*, 944 P.2d 984, 994 (Or. Ct. App. 1997).

federal requirements that would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce. These state requirements therefore escape preemption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such as pacemakers.¹²⁴

While the *Mears* Court was technically correct in noting that Part V of *Medtronic* was a majority opinion, the court failed to understand that Justice Breyer had written separately to distinguish himself from the majority on this point. Breyer argued that the MDA preempts a “requirement that takes the form of a standard of care or behavior imposed by a state law tort action.”¹²⁵ The downfall of Medtronic’s argument, according to Justice Breyer, was that the 510(k) process did not impose specific federal requirements.¹²⁶

V. SUPREME COURT ANALYSIS 10 YEARS AFTER MEDTRONIC V. LOHR – THE LIKELIHOOD OF PREEMPTION IN PMA CASES

Within the past few months, our nation has witnessed the rise of two new Justices to the Supreme Court, Chief Justice John Roberts and Justice Samuel Alito. Within the focus of preemption under the MDA, the vote of these two justices will prove to be vital. Both

¹²⁴ *Id.* at 990 (quoting from *Medtronic v. Lohr*, 518 U.S. 470, 500 (1996)); *See also* *Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997) (making a similar argument in the investigational device exemption arena).

¹²⁵ *Lohr*, 518 U.S. at 504-505 (Breyer, J. concurring in part and concurring in the judgment).

¹²⁶ *Id.*

former Chief Justice William Rehnquist and retired Justice Sandra Day O'Connor were votes in *Medtronic* that favored somewhat broad preemption.¹²⁷ In Justice O'Connor's opinion from *Medtronic*, she noted that the 510(k) process merely evaluated whether the device could be deemed "substantially equivalent" to a device already on the market, and thus placed no requirements on the device.¹²⁸ However, Justice O'Connor argued that the generally applicable manufacturing and labeling regulations imposed by the FDA are stringent enough to create specific requirements on a device, thus preempting any tort claims.¹²⁹ In turn, one can fairly assume that Justices subscribing to such an opinion would find preemption under the even more rigorous PMA process.

A. *A New Court Rises? – The Impact of Chief Justice Roberts and Justice Alito*

Both Chief Justice Roberts and Justice Alito have been exposed to the debate over whether the PMA process preempts state common law claims.

1. *English v. Mentor Corp. – Alito's Alignment*

Prior to the Supreme Court's decision in *Medtronic*, Justice Alito took part in *English v. Mentor Corp.*, a decision regarding the preemptive effect of the 510(k) process under the MDA.¹³⁰ In *English*, the plaintiff had brought a claim for damages against the

¹²⁷ *Lohr*, 518 U.S. at 513-514 (O'Connor, J., concurring in part and dissenting in part) (noting that in Justice O'Connor's opinion she felt that some, if not all, of the Lohrs' common law claims regarding labeling and manufacturing were preempted because of the requirements imposed by the FDA through such regulations as the Good Manufacturing Practices and federal labeling requirements).

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995) (per curiam) (oral arguments heard by Judge Alito, Judge Nygaard and Judge Cowen).

manufacturer of an inflatable penile prosthesis.¹³¹ The device had been cleared for marketing under the 510(k) exemption to the PMA requirement.¹³² The Court held that the 510(k) process did place specific requirements on the inflatable penile prosthesis and therefore English's claims were preempted.¹³³ While this decision would later be indirectly overturned by the Supreme Court's decision in *Medtronic*, one can infer that if Alito did not dissent from the per curiam opinion, he likely decided that the more rigorous PMA process also preempts common law claims.

2. Friend of the Court - Chief Justice John Roberts

Chief Justice John Roberts authored an amicus brief filed with the Supreme Court in the *Medtronic* case, and argued that the 510(k) process imposes specific federal requirements on a device and should therefore preempt all of Lora Lohr's claims.¹³⁴ The brief is dedicated to the argument that Congress purposely wanted to preempt common law tort claims against medical device manufacturers.¹³⁵ Doing so, Chief Justice Roberts argues, will allow manufacturers to continue developing potentially life-saving devices that will further patient care and allow those in our society to lead fuller lives.¹³⁶ Chief Justice Roberts stated:

The divergent patchwork of state products liability laws in this country imposes a 'liability tax' that is passed on to all of us in the form of increased product costs and insurance premiums. In the case of medical products,

¹³¹ *Id.* at 478.

¹³² *Id.* at 480.

¹³³ *Id.* at 483-84.

¹³⁴ Brief Supporting Petitioner/Cross Respondent, *supra* note 100.

¹³⁵ *Id.*

¹³⁶ *Id.* at 4.

however, products liability laws exact an additional, far greater societal toll: they stunt the development of new and improved medical products and drive existing products from the marketplace. Thus, many potentially life-saving medical products are not developed by manufacturers today because of liability concerns, and existing, FDA-cleared products are pulled from the market by manufacturers facing massive liability in suits brought by users, even though in many cases there is no scientifically credible evidence that these products are harmful. The quality of patient care in this country suffers as a result.¹³⁷

As this was Chief Justice Roberts' only exposure to the preemption realm of the MDA, it may prove decisive once he has a vote to cast in an actual Supreme Court decision. If Chief Justice Roberts thought the 510(k) process should preempt common law tort claims, the logical conclusion is that he would also vote for preemption in PMA medical device cases.

B. Justice Scalia & Justice Thomas – The Rocks of Preemption

In *Bates v. Dow Agrosciences*, the Supreme Court examined whether the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) preempts state-law claims for damages.¹³⁸ FIFRA contains an express preemption provision similar to the one found in the

¹³⁷ *Id.*

¹³⁸ 125 S. Ct. 1788 (2005).

MDA.¹³⁹ The Court ultimately remanded the case to the lower court to determine whether particular common law duties were equivalent to FIFRA's misbranding standards.¹⁴⁰ If equivalent, the claims would survive preemption analysis.

Justice Thomas, joined by Justice Scalia, wrote separately to stress that the majority had left out a step in its reasoning with regard to a few of the claims: “

A state law cause of action, even if not specific to labeling, nevertheless imposes a labeling requirement “in addition to or different from” FIFRA’s when it attaches liability to statements on the label that do not produce liability under FIFRA. The state-law cause of action then adds some supplemental requirement of truthfulness to FIFRA’s requirement that labeling statements not be “false or misleading.”¹⁴¹

The same reasoning applies to state law causes of action against medical devices that have received approval under the PMA process. During PMA, the FDA extensively reviews the device’s design, labeling, warnings, safety and effectiveness. As mentioned, the FDA often tells manufacturers what to specifically include in its warnings.¹⁴² Should no specific instruction need to be given, the FDA has determined that there is a reasonable assurance of safety and effectiveness. Thus, due to these stringent requirements, imposing liability on a manufacturer of a PMA device when liability would not

¹³⁹ See 7 U.S.C. § 136v(b) (2006) (“Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or those required under this subchapter”).

¹⁴⁰ *Bates*, 125 S. Ct. at 1803.

¹⁴¹ *Bates*, 125 S. Ct. at 1805 (Thomas, J., concurring in the judgment in part and dissenting in part).

¹⁴² See e.g. cases cited *supra* note 96.

attach under the FDCA creates a requirement different from or in addition to those already required by the FDA, and preemption therefore applies.

C. Justice Breyer – The Swing Vote

As mentioned, Justice Breyer’s opinion in *Medtronic* focused on two main reasons why preemption was not valid. First, as Breyer was unable to determine what Congress intended as the scope of preemption under the MDA, he argued that “courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations or other administrative actions will have preemptive effect.”¹⁴³ This statement even comports with Justice Stevens’ opinion that “the [FDA] is uniquely qualified to determine whether a particular form of the state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’”¹⁴⁴ Breyer went on to argue that one can determine whether the FDA intends for rules or regulations to have preemptive effect by looking to “statements in ‘regulations, preambles, interpretive statements, and responses to comments,’ as well as through the exercise of [the FDA’s] explicitly designated power to exempt state requirements from preemption.”¹⁴⁵

After years of silence regarding the preemptive scope of its preemption regulation, as it pertains to the 510(k) process and the PMA process, the FDA recently issued an interpretive statement of what it feels is preempted. In *Horn v. Thoratec Corp.*, the Third Circuit received an amicus curiae brief from the FDA prior to issuing a decision regarding preemption analysis for PMA medical devices. In the brief, the FDA notes the substantial difference between the PMA process and the 510(k) process:

¹⁴³ *Medtronic v. Lohr*, 518 U.S. 470, 505 (1996) (Breyer, J., concurring in part and concurring in the judgment).

¹⁴⁴ *Id.* at 496 (plurality) (Stevens, J.).

¹⁴⁵ *Id.* at 506 (Breyer, J., concurring in part and concurring in the judgment).

A manufacturer can obtain an FDA finding of ‘substantial equivalence’ by submitting a pre-market notification to the agency in accordance with section 510(k) of the [Act]. A device found to be ‘substantially equivalent’ to a predicate device is said to be ‘cleared’ by FDA (as opposed to ‘approved’ by the agency under a PMA). A pre-market notification . . . is thus entirely different from a PMA, which must include data sufficient to demonstrate to FDA that the device is safe and effective. The number of medical devices that receive PMA review each year is dwarfed by the number of those that are marketed pursuant to cleared Section 510(k). In fiscal year 2003, for example, original PMA’s represented only 54 of 9,872 major submissions received. The previous fiscal year, original PMA’s accounted for 49 of 10,323 total submissions.¹⁴⁶

It appears then, that the FDA considers these two processes to be completely different: the 510(k) process is really similar to a licensing process, while the PMA process actually results in FDA approval of the device for safety and effectiveness concerns. Justice Breyer, and even other members of the Court that joined Justice Stevens’ opinion, may find this FDA interpretation to be convincing, if not dispositive of the issue.

The second reason Justice Breyer did not find preemption in *Medtronic* was because even if one could argue that FDA imposes requirements on 510(k) devices, none of those requirements are

¹⁴⁶ Horn v. Thoratec Corp., 376 F.3d 163, 167 (3d Cir. 2004).

actually specific to the device.¹⁴⁷ Given the aforementioned difference between the 510(k) process and the PMA process, and the fact that during the PMA process the FDA often does draft or require specific warnings or device designs, Justice Breyer will be hard pressed to argue that the FDA does not make specific requirements of devices during the PMA process.

Thus, it appears that at least five Justices are likely to adopt a similar rule to that put forward by the 7th Circuit. While by no means is this analysis conclusive evidence of how the Supreme Court may eventually decide the issue, it does provide educated speculation as to whether a clear majority exists. Time will only tell whether such speculation has been fruitful.

CONCLUSION

“[M]edical devices—like all man-made devices—malfunction. No federal regulatory or state tort law regime can prevent that.”¹⁴⁸ However, to ensure that medical device innovation continues throughout the 21st century, reasonable protections must be afforded to medical device manufacturers. The 7th Circuit’s rule regarding preemption for PMA medical devices is one reasonable avenue of protecting a small percentage of medical device manufacturers, while balancing the competing goals of medical device innovation and protection of the public.

¹⁴⁷ *Lohr*, 518 U.S. at 507 (Breyer, J., concurring in part and concurring in the judgment).

¹⁴⁸ Brief Supporting Petitioner/Cross Respondent, *supra* note 100, at 27.